REMARKS

Claims 40 to 44 and 69 to 74 are under consideration in the application. Claim 71 has been amended to correct a typographical error. Claim 73 has been amended to remove text that was inadvertently bracketed, rather than removed, in the Amendment filed August 24, 2001. The amendments add no new matter.

Rejections Under 35 U.S.C. §102

The Examiner maintained the rejection of claims 71 and 73 under 35 U.S.C. §102(a) as allegedly being anticipated by Lasken et al. (JBC, 271:17692-17696, 1996) ("Lasken"). Action at page 2. Applicants respectfully traverse this rejection. For a reference to anticipate the claimed invention under 35 U.S.C. § 102, the reference must describe the invention such that "each and every limitation is found either expressly or inherently" within it. *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370, 62 USPQ2d 1865, 1869 (Fed. Cir. 2002) (citations omitted); *see* MPEP § 2131 (8th ed. 2001) ("to anticipate a claim, the reference must teach every element of the claim"). The Examiner has failed to establish a *prima facie* case under 35 U.S.C. § 102, because the cited reference does not disclose each element of claims 71 and 73.

Claim 71 recites methods of enhancing a nucleic acid polymerase reaction comprising performing the reaction in the presence of one or more certain options, including a dUTPase activity. The Examiner has failed to explain how Lasken shows a dUTPase activity. In describing Lasken, the Examiner states that "dUTP is added to a polymerase reaction which resulted in a longer product (page 17694, col. 2)." Action at page 3-4. The Examiner reiterates, "the reference only requires dUTP to be present in

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

the polymerase reaction." Action at page 4. Laskin, however, does not suggest that the presence of dUTP indicates the presence of "a dUTPase activity." The Examiner has not identified a dUTPase activity in Lasken.

The portion of Lasken cited by the Examiner discusses a polymerization reaction in which dTTP was withheld and then replaced with dUTP. The addition of dUTP allowed polymerization to resume. The authors concluded that dUTP can be incorporated into a polymerized strand in a polymerization reaction lacking dTTP. However, as pointed out in the present specification, Lasken fails to mention "any dUTPase activity or the possible effect of dUTPase activity on polymerization reactions." Present specification at page 5. Indeed, Lasken reports that "the presence of dUTP in the reaction does not inhibit incorporation of normal dNTPs." Lasken at page 17696, col. 1, lines 28-29. Thus, Lasken does not teach a method of enhancing a polymerase reaction comprising performing the reaction in the presence of dUTPase activity as recited in claim 71.

For at least that reason, claim 71 is not anticipated by Lasken. Claim 73 depends from claim 71. Thus, claim 73 is not anticipated by Lasken.

Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. §102.

Double Patenting

The Examiner rejected claims 40 to 44 and 69 to 74 under the judicially-created doctrine of obviousness-type double patenting over claims 1 to 29 of U.S. Pat. No. 6,183,997 B1. Office Action, pages 4-5 section 7.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

Although Applicants indicated that they would file a terminal disclaimer in the Response filed January 3, 2003, upon further reflection, Applicants assert that the rejection is improper in view of restriction requirements in U.S. Application Serial Nos. 08/822,774 (the '774 application) and 08/957,709 (the '709 application). Accordingly, Applicants traverse the rejection.

U.S. Patent No. 6,183,997 B1 issued from the '774 application. In an Office Action mailed October 5, 1998, in the '774 application, Group II was restricted from Group I. Claims 40 to 44 of the present application fall within Group II and claims 1 to 29 of U.S. Patent No. 6,183,997 B1 fall within Group I. A copy of that Office Action is attached. The '709 application is a continuation-in-part of the '774 application. In an Office Action mailed October 5, 1998, in the '709 application, Group III was restricted from Group I. Claims 40 to 44 and 69 to 74 of the present application fall within Group III and claims 1 to 29 of U.S. Patent No. 6,183,997 B1 fall within Group I. A copy of that Office Action is attached.

The present application is a divisional application of the '709 application. According to 35 U.S.C. § 121, a "patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application . . ." See also *The Manual of Patent Examining Procedure, Eighth Edition*, August 2001 (MPEP) § 804.01. Thus, the double patenting rejection of claims 40 to 44 and 69 to 74 in view of claims 1 to 29 of U.S. Pat. No. 6,183,997 B1 is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of that rejection.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

Conclusion

Applicants request reconsideration and withdrawal of all rejections. Applicants respectfully submit that claims 40 to 44 and 69 to 74 are in condition for allowance. In the event the Examiner does not find the claims allowable, Applicants request that the Examiner contact the undersigned at (650) 849-6676 to set up an interview.

If there is any fee due in connection with the filing of this Response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: June 16, 2003

By: _____

Clifford E. Ford
Reg. No. 52,903

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trad mark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/822,774	03/21/97	HENDRETT	H

HM31/1005

FINNEGAN, HENDERSON, FARABOW, GARRETT &
DUNNER, LLP
1300 I STREET N W
WASHINGTON DC 20005-3315

EXAMINER	
HOUTTEMAN	

ART UNIT	PAPER NUMBER

DATE MAILED: 10/05/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Docketed 10-9-98 Attorney MPB-JKM
Case 4121-006
Due Date 1-4-98
Action ELECTION DUE
By

PTO-90C (Rev. 2/95)
*U.S. GPO: 1997-417-381/62715

2 - Mail Copy

Office Action Summary	Application No. 08/822,774	Applicant(s) Hogrefe
	Examiner Scott W. Houtteman	Group Art Unit 1634

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *30 days* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-57* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-57* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-39, 45 and 46, drawn to components having polymerase enhancing activity, mixtures, kits and antibodies, classified in class 530, subclass 350.

II. Claims 40-44, drawn to methods of enhancing polymerase activity, classified in class 435, subclass 4.

III. Claim 47, drawn to a method of purifying polymerase enhancing activity, classified in class 210, subclass 656.

IV. Claims 48-51, drawn to methods of activity identification, classified in class 435, subclass 7.4.

V. Claims 52-57, drawn to methods of DNA identification, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons: Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In this case the product can be made by cloning the corresponding gene or by isolating the product from nature.

Inventions I is related to each of the inventions, II, IV and V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In this case the product has the materially different uses, II, IV and V.

The methods of II, IV and V are distinct. These methods have different reagents, different steps and yield different products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
October 2, 1998

SCOTT W. HOUTTEMAN
PRIMARY EXAMINER

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/957,709	10/24/97	HOGREFE H	1485/41[illegible]

43163CP

HM31/1005
EVENSON MCKEOWN EDWARDS AND LENAHAN
1200 G STREET NW SUITE 700
WASHINGTON DC 20005

EXAMINER	
HOUTTEMAN,S	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/05/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Docketed 10-13-98 Attorney MPB JKM
Case 0412-0116-01
Due Date 11-4-98 w/ext
Action Resp/Oject Due
By JEN

Office Action Summary	Application No. 08/957,709	Applicant(s) Hogrefe et al.
	Examiner Scott W. Houtteman	Group Art Unit 1634

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *30 days* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-94* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-94* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-23, 28-39, 45, 46, 59-66, 77-80, 85, 87-92, drawn to compositions comprising polymerase enhancing activity, mixtures, kits, complexes and proteins, classified in class 530, subclass 350.

II. Claims 24-27, 58, 67, 68, 84, drawn to DNA and DNA replication kits, classified in class 536, subclass 23.2.

III. Claims 40-44, 69-74, drawn to Methods of enhancing polymerase, classified in class 435, subclass 4.

IV. Claim 47, drawn to a method of purification, classified in class 210, subclass 656.

V. Claims 48-57, 75 and 76, drawn to methods of detection of polymerase enhancing activity, classified in class 435, subclass 6.

VI. Claims 81-83 and 86, drawn to methods of protein production, classified in class 435, subclass 69.2.

VII. Claims 93 and 94, drawn to computer readable sequences and methods of computer screening, classified in class 706, subclass 932.

2. The inventions are distinct, each from the other for the following reasons: Inventions IV and VI are both related to invention I as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In this case the product can be made by the two materially different processes, IV and VI.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In this case the product can be used in a protein purification process as well as a method of enhancing polymerase.

The nucleic acid of group II and the proteins of group I are chemically different with different structures, functions, and properties and are therefore distinct. Also, given the nucleic acid, one of ordinary skill in the art could not reasonably expect to come up with the active native protein. Recombinant proteins do not often fold up into native conformation. In addition, the protein can be obtained by a method other than recombinant DNA technology, for example, by purification from natural sources.

The methods of groups I, III, IV, IV and VII are distinct. They have different reagents, different steps and yield different products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
October 2, 1998

SCOTT W. HOUTTEMAN
PRIMARY EXAMINER